METHODS FOR REDUCING DISTAL EMBOLIZATION

Background of the Invention

Field of the Invention

The present invention relates generally to an improved method for reducing distal embolization during treatment of emboli, thrombi and other types of occlusions in the human arterial or venous system. The method is particularly well suited for use when treating stenoses or occlusions within saphenous vein grafts, coronary arteries, cerebral arteries and similar vessels.

Description of the Related Art

Human blood vessels often become occluded or completely blocked by plaque, thrombi, emboli or other substances, which reduces the blood carrying capacity of the vessel. Should the blockage occur at a critical location in the circulation, serious and permanent injury, or death, can occur. To prevent this, some form of medical intervention is usually performed when significant occlusion is detected, such as during an acute myocardial infarction (AMI).

Coronary heart disease is the leading cause of death in the United States and a common occurrence worldwide. Damage to or malfunction of the heart is caused by narrowing or blockage of the coronary arteries (atherosclerosis) that supply blood to the heart. The coronary arteries are first narrowed and may eventually be completely blocked by plaque, and may further be complicated by the formation of thrombi (blood clots) on the roughened surfaces of the plaques. AMI can result from atherosclerosis, especially from an occlusive or near occlusive thrombus overlying or adjacent to the atherosclerotic plaque, leading to death of portions of the heart muscle. Thrombi and emboli also often result from myocardial infarction, and these clots can block the coronary arteries, or can migrate further downstream, causing additional complications.

Various types of intervention techniques have been developed which facilitate the reduction or removal of the blockage in the blood vessel, allowing increased blood flow through the vessel. One technique for treating stenosis or occlusion of a blood vessel is balloon angioplasty. A balloon catheter is inserted into the narrowed or blocked area, and

the balloon is inflated to expand the constricted area. In many cases, near normal blood flow is restored. It can be difficult, however, to treat plaque deposits and thrombi in the coronary arteries, because the coronary arteries are small, which makes accessing them with commonly used catheters difficult.

Other types of intervention include atherectomy, deployment of stents, introduction of specific medication by infusion, and bypass surgery. Each of these methods is not without the risk of embolism caused by the dislodgment of the blocking material which then moves downstream. In addition, the size of the blocked vessel may limit percutaneous access to the vessel.

There is a need for an improved method of reducing distal embolization during treatment of occluded vessels that can be performed regardless of the size of the blood vessel.

Summary of the Invention

Described below is an improved method for preventing distal embolization during removal of plaque, thrombi or other occlusions from a blood vessel. In a preferred embodiment of the invention, aspiration is performed while advancing a guidewire across the site of the occlusion in a proximal to distal direction to prevent distal embolization. An aspiration catheter is delivered over the guidewire until the distal ends of the guidewire and aspiration catheter are just proximal to the site of the occlusion. While aspirating, the occlusion in the vessel is crossed with both the guidewire and the catheter in a proximal to distal direction. In a preferred embodiment, the distal tip of the aspiration catheter is no more than 2 cm, more preferably no more than 0.5-1 cm, behind or proximal to the distal tip of the guidewire during crossing. The distal end of the aspiration catheter is then moved back across the occlusion, while continuously aspirating, to ensure the removal of any particles which may be created during the delivery of the guidewire to a position distal to at least a portion of the occlusion. Aspiration from proximal to distal, and distal to proximal, can be repeated as many times as necessary to completely aspirate all particles. These steps are all performed prior to any occlusion of the vessel using an occlusive device at a site distal to the occlusion, and treatment of the occlusion, as described below.

In another preferred embodiment of the invention, a guidewire having an occlusive device on its distal end is advanced across the occlusion such that the occlusive device is

distal to the occlusion, where it is then actuated. An aspiration catheter is delivered over the guidewire to a location proximal to the occlusion. Delivery of the aspiration catheter can occur before or after actuation of the occlusive device. While the occlusive device is actuated, the distal end of the aspiration catheter is moved in a proximal to distal direction across at least a portion of the occlusion while aspirating at the same time. Alternatively, aspiration may begin after the distal end of the aspiration catheter is moved distal to at least a portion of the occlusion, and the aspiration catheter may be moved in a distal to proximal direction. Furthermore, regardless of whether aspiration begins proximal or distal to the occlusion, aspiration may continue in both proximal to distal and distal to proximal directions and repeated as necessary to completely aspirate particles.

The aspiration method disclosed herein can be used in any vessel of the body where the pressure is at least 0.2 psi at any time during the diastolic/systolic cycle of the heart, and, preferably, is about 1.2 psi, and is capable of providing a flow rate of at least 5 cc/minute when not occluded. Thus, although the pressure within any vessel may fall below 0.2 psi during relaxation between heartbeats, so long as the pressure created by the heartbeat rises to at least 0.2 psi, the pressure within the vessel will be sufficient.

The present method is particularly suited for use following myocardial infarction, and in removal of occlusions from saphenous vein grafts, coronary and carotid arteries, and vessels having similar pressures and flow.

In a preferred embodiment of the method of the present invention, a guide catheter is first introduced into the patient's vasculature through an incision made in the femoral artery in the groin and is used to guide the insertion of other catheters and devices to the desired site. A guidewire is then advanced until its distal end reaches a site proximal to the occlusion. Fluoroscopy is typically used to guide the guidewire and other devices to the desired location within the patient. The devices are frequently marked with radiopaque markings to facilitate visualization of the insertion and positioning of the devices within the patient's vasculature.

In contrast to previous methods, in one embodiment the guidewire does not cross the occlusion prior to aspiration with an aspiration catheter or other suitable catheter which can provide aspiration pressure. Instead, an aspiration catheter is inserted over the guidewire and the two are concomitantly moved past the occlusion, proximal to distal,

while aspirating, to prevent material which dislodges or breaks off the occlusion from entering the vasculature and producing distal emboli.

A guidewire having an occlusive device on its distal end is preferably used in the present method. The method can be effectively carried out, however, using a number of guidewires or catheters that perform the function of occluding the vessel and allowing for the slidable insertion of various other catheters and devices. A standard guidewire can also be used to initially cross the occlusion, and then exchanged with a guidewire having an occlusive device at its distal end. When the standard guidewire is used, it may also be delivered with the aspiration catheter so that both are moved past the occlusion while aspirating. The occlusive device should be capable of preventing the migration of particles and debris from the working area, either through total or partial occlusion of the vessel. The occlusion of the vessel need not be complete.

As the guidewire and aspiration catheter cross the occlusion, blood enters the vessel and keeps any particles dislodged during the procedure from flowing in a distal to proximal direction. In addition, the blood pressure and flow provides the irrigation necessary for aspiration.

After the distal end of the guidewire having an occlusive device is delivered past the site of the occlusion and aspiration is complete, the occlusive device is activated, preventing particles and debris from travelling downstream. Therapy can then be performed to remove or reduce the occlusion. A therapy catheter can be used if desired. The therapy catheter can be any of a number of devices, including a balloon catheter used to perform angioplasty, a catheter which delivers a stent, a catheter for delivering enzymes, chemicals, or drugs to dissolve and treat the occlusion, an atherectomy device, or a laser or ultrasound device used to ablate the occlusion. Alternatively, the therapy catheter can be eliminated and use of the guide catheter or the aspiration catheter alone can be used to aspirate the occlusion. This method is especially useful to remove emboli from the coronary arteries following acute myocardial infarction, because the aspiration catheter can be made small enough to enter the coronary arteries.

Once the desired therapy is performed, the therapy catheter is withdrawn from the patient's body and the aspiration catheter can once again be delivered over the guidewire if desired to remove any particles or debris created during therapy.

The method described herein provides an improved method for reducing distal embolization during treatment of emboli, thrombi and other types of occlusions in the human arterial or venous system, and is especially useful following myocardial infarction.

Further aspects, features and advantages of the present invention will become apparent to those skilled in the art from the following detailed description of the preferred embodiments and the drawings referenced herein, the invention not being limited to any particular embodiment.

Brief Description of the Drawings

FIGURE 1 shows an embodiment of a syringe assembly having features in accordance with the present invention and operably coupled to an illustrative inflation adapter at a proximal portion of a balloon catheter;

FIGURE 2 is a side view of a balloon catheter of the present invention.

FIGURE 3A is a longitudinal cross-sectional view of a balloon catheter incorporating a multiple tapered core wire.

FIGURE 3B is an enlarged view of the proximal end of the balloon of **FIGURE 3A**.

FIGURE 4 is a schematic representation of an introducer arrangement including a protective sheath assembly to introduce a catheter with a balloon into a blood vessel;

FIGURE 5 is a side cross-sectional view of the protective sheath assembly of **FIGURE 4**;

FIGURE 6 is an enlargement of the transition section of the protective sheath assembly of **FIGURE 5** as indicated by line 6-6;

FIGURES 7A AND 7B show the open and closed low profile catheter valve positions, respectively;

FIGURE 8 shows a perspective view of the catheter valve and balloon catheter of **FIGURE 1** placed within an open inflation adapter;

FIGURE 9 shows another embodiment of an inflation adapter having a catheter valve and balloon catheter placed therewithin;

FIGURES 10 AND 11 show alternative connections of a low volume syringe having features in accordance with the present invention;

FIGURE 12 shows a cross-sectional view along the longitudinal axis of a preferred embodiment of the low-volume syringe of the present invention;

FIGURE 13 shows an end view of the low-volume syringe of **FIGURE 12**;

FIGURE 14 is an exploded perspective view of a low-volume syringe having features in accordance with the present invention;

FIGURES 15-18 are cross-sectional views showing the syringe of **FIGURE 14** in various stages of operation;

FIGURE 19 is a perspective exploded view of another embodiment of an integrated inflation/deflation syringe having features in accordance with the present invention;

FIGURE 20 is a cross-sectional view of the syringe of **FIGURE 19**;

FIGURE 21 is an exploded perspective view of yet another embodiment of the low-volume syringe having features in accordance with the present invention;

FIGURES 22 and 23 are cross-sectional views of the syringe of **FIGURE 21**, showing a syringe plunger engaged with a lock tab;

FIGURE 24 is a plan view of a lock body installed on the syringe of **FIGURE 21**, showing a lock tab in a thread-engaging position;

FIGURE 25 is a plan view of the lock body of **FIGURE 28**, showing the lock tab in an unlocked position relative to the plunger;

FIGURES 26-27 are cross-sectional views of the syringe of **FIGURE 21**, showing the plungers disengaged from the thread tab;

FIGURE 28 is a cross-sectional view of another embodiment of an integrated inflation/deflation syringe having features in accordance with the present invention;

FIGURES 29-31 are cross-sectional views showing the syringe of **FIGURE 28** in various operational stages;

FIGURE 32 is an end view of a detent mechanism for use with the syringe of **FIGURE 28**;

FIGURE 33 shows an alternative syringe assembly;

FIGURE 34 is a perspective view of a preferred embodiment of an integrated inflation/deflation device having features in accordance with the present invention;

FIGURE 35 is a perspective view of the device of **FIGURE 34**, shown operably coupled to an illustrative inflation adapter and a proximal portion of a balloon catheter;

FIGURE 36 is a side view of a syringe assembly portion of the device of **FIGURE 34**;

FIGURE 37 is a top view of the device of **FIGURE 34**;

FIGURE 38 is a left side view of the device of **FIGURE 34**;

FIGURE 39 is a right side view of the device of **FIGURE 34**;

FIGURE 40 is a front view of the device of **FIGURE 34**;

FIGURE 41 is an inside view of the right housing of the device of **FIGURE 34**;

FIGURE 42 is an inside view of the left housing of the device of **FIGURE 34**;

FIGURE 43 is a cross-sectional view of the device of **FIGURE 37**, taken along lines 43-43;

FIGURE 44 is a cut-away view of the device of **FIGURE 43**, taken along lines 44-44;

FIGURE 45 is an exploded perspective view of another preferred embodiment of an integrated inflation/deflation device having features in accordance with the present invention;

FIGURE 46 is an exploded perspective view of a knob assembly for use with the device of **FIGURE 45**;

FIGURE 47 is a top view of the device of **FIGURE 45**;

FIGURE 48 is a side view of the device of **FIGURE 45**, with a portion of the housing removed;

FIGURE 49 is a top plan view of an inflation syringe plunger adapted for use with the device of **FIGURE 45**;

FIGURE 50 is a partially cutaway detailed side view of an inflation barrel of the device of **FIGURE 45**;

FIGURE 51 is an exploded perspective view of a reservoir syringe plunger for use with the device of **FIGURE 45**.

FIGURES 52A-H are perspective views of the movement of a guidewire and an aspiration catheter in a totally occluded blood vessel, placement of an occlusive balloon, and treatment of the occlusion.

FIGURES 53A-G are perspective views of the movement of a guidewire and an aspiration catheter in a partially occluded blood vessel, placement of an occlusive balloon, and treatment of the occlusion.

FIGURES 54A-54F are perspective views of the movement of a guidewire with an occlusive balloon and an aspiration catheter in a partially occluded blood vessel.

Detailed Description of the Preferred Embodiments

The present invention involves a method for advancing a guidewire into position in the vasculature of a patient prior to therapy on plaque, a thrombus, emboli, or other occluding substance. The preferred devices used during the method will be described first, followed by a description of the preferred method of use.

I. Overview Of Occlusion System

A. Syringe Assembly

The preferred embodiments of the present invention may comprise or be used in conjunction with a syringe assembly such as that generally illustrated in **FIGURE 1**. Also shown in **FIGURE 1** is an illustrative connection of the syringe assembly 50 to an occlusion balloon guidewire catheter 70 utilizing an inflation adapter 54. The syringe assembly 50, comprising the inflation syringe 60 and a larger capacity or reservoir syringe 62, is attached via tubing 64 to the inflation adapter 54 within which a low profile catheter valve 66 and the balloon catheter 70 are engaged during use.

The catheter valve 66, described in more detail below in connection with **FIGURES 7A** and **7B**, is attached to an open proximal end of the catheter 70. The low volume syringe 60 is used to inject inflation fluid through the adapter 54 and valve 66 into a lumen of the hollow catheter 70, and into the balloon 72. The inflation adapter 54, described in more detail below in connection with **FIGURE 8**, is used to open and close the valve 66 to regulate the inflation of the balloon 72 mounted on the distal end of the catheter 70. Nevertheless, it will be emphasized that other types of adapters and/or valves can be employed with the inflation syringe and/or syringe assembly described herein, in order to achieve rapid and accurate inflation/deflation of medical balloons or other non-balloon medical devices. Therefore, although the present inflation is illustrated in connection with a low volume occlusion balloon 72, other types of balloons and non-balloon devices can benefit from the advantages of the inflation described herein.

The balloon 72 is mounted on a distal end of a hollow guidewire 70 which defines the inflation lumen for the balloon 72, and the syringe 60 and/or syringe assembly 50 is connected at the proximal control end 33 of the guidewire 70. Prior to use of the low volume syringe 60 to inflate the balloon 72 to the proper size for the vascular segment to be treated, the guidewire 70 and balloon 72 are first "primed" or evacuated. The reservoir syringe 62 of the assembly 50 may be used for the evacuation.

B. Occlusion Balloon Guidewire

The occlusion balloon/guidewire system generally illustrated in **FIGURE 1** performs the function of occluding a vessel and allowing for the slidable insertion or advancement of various other catheters and devices. The term "catheter" as used herein is therefore intended to include both guidewires and catheters with these desired characteristics. The term "occlusion" refers to both partial and total occlusion of a vessel.

As shown in **FIGURE 2**, a balloon guidewire catheter 70 generally comprises an elongate flexible tubular body 80 extending between a proximal control end 82, corresponding to a proximal section of the tubular body 80, and a distal functional end 84, corresponding to a distal section of tubular body 80. Tubular body 80 has a central lumen 86, which extends between ends 82 and 84. An inflation port 90 is provided on tubular body 80 near the proximal end 82. Inflation port 90 is in fluid communication with lumen 86 such that fluid passing through inflation port 90 into or out of lumen 86 may be used to inflate or deflate an inflatable balloon 72 in communication with lumen 86. Further details are disclosed in assignee's co-pending application entitled LOW PROFILE CATHETER VALVE AND INFLATION ADAPTER, Application Serial No. 08/975,723, filed November 20, 1997, the entirety of which is hereby incorporated by reference.

The length of tubular body 80 may be varied considerably depending on the desired application. For example, when catheter 70 serves as a guidewire for other catheters in a conventional percutaneous transluminal coronary angioplasty procedure involving femoral artery access, tubular body 80 is comprised of a hollow hypotube having a length in the range from about 160 to about 320 centimeters, with a length of about 180 centimeters being optimal for a single operator device, or 300 centimeters for

over the wire applications. Alternatively, for a different treatment procedure not requiring as long a length of tubular body 80, shorter lengths of tubular body 80 may be provided.

Tubular body 80 generally has a circular cross-sectional configuration with an outer diameter within the range from about 0.008 inches to 0.14 inches. In applications where catheter 70 is to be used as a guidewire for other catheters, the outer diameter of tubular body 80 ranges from 0.010 inches to 0.038 inches and preferably is about 0.014 to 0.020 inches in outer diameter or smaller. Noncircular cross-sectional configurations of lumen 86 can also be adapted for use with the catheter 70. For example, triangular, rectangular, oval and other noncircular cross-sectional configurations are also easily incorporated for use with the present invention, as will be appreciated by those of skill in the art. The tubular body 80 may also have variable cross-sections.

The tubular body 80 has sufficient structural integrity or "pushability" to permit catheter 70 to be advanced through the vasculature of a patient to distal arterial locations without buckling or undesirable kinking of tubular body 80. It is also desirable for the tubular body 80 to have the ability to transmit torque such as in those embodiments where it may be desirable to rotate tubular body 80 after insertion into a patient. A variety of biocompatible materials known by those of skill in the art to possess these properties and to be suitable for catheter manufacture may be used to produce tubular body 80. For example, tubular body 80 may be made of a stainless steel material such as ELGILOY™, or may be made of polymeric material such as PEEK, nylon, polyimide, polyamide, polyethylene or combinations thereof. In one preferred embodiment, the desired properties of structural integrity and torque transmission are achieved by forming the tubular body 80 out of an alloy of titanium and nickel, commonly referred to as nitinol. In a more preferred embodiment, the nitinol alloy used to form the tubular body 80 is comprised of about 50.8% nickel and the balance titanium, which is sold under the trade name TINEL™ by Memry Corporation. It has been found that a catheter tubular body having this composition of nickel and titanium exhibits an improved combination of flexibility and kink resistance in comparison to other materials. Other details regarding construction of catheter 70 may be found in assignee's copending applications entitled HOLLOW MEDICAL WIRES AND METHODS OF CONSTRUCTING SAME, Application Serial No. 08/812,876, filed March 6, 1997, SHAFT FOR MEDICAL

CATHETERS, Application Serial No. 09/026,105, filed February 19, 1998, and FLEXIBLE CATHETER, Application Serial No. 09/253,591, filed February 22, 1999, all of which are hereby incorporated by reference in their entirety.

As illustrated in **FIGURE 2**, an expandable member such as inflatable balloon 72 is mounted on the distal end 84 of tubular body 80. In one preferred embodiment, balloon 72 is a compliant balloon formed of a material comprising a block polymer of styrene-ethylene-butylene-styrene (SEBS), as disclosed in assignee's copending application entitled BALLOON CATHETER AND METHOD OF MANUFACTURE, Application Serial No. 09/026,225, filed on February 19, 1998, the entirety of which is hereby incorporated by reference. The balloon 72 may be secured to the tubular body 80 by any means known to those skilled in the art, such as adhesives or heat bonding. For example, for attachment of a SEBS balloon to a nitinol tube, a primer such as 7701 LOCTITE (TM) by Loctite Corporation is preferably used along with cyanoacrylate adhesive such as LOCTITE-4011.

The balloon 72 described in the preferred embodiments preferably has a length of about 5 to 9 mm and more preferably about 6-8 mm. Other expandable members are suitable for the catheter 70, such as those disclosed in assignee's copending application entitled OCCLUSION OF A VESSEL, Application Serial No. 09/026,106, filed February 19, 1998, the entirety of which is hereby incorporated by reference.

With next reference to **FIGURES 3A and 3B**, a core wire 140 is provided inside the lumen 86. Coils 132 extend from the distal end of the balloon 72, surround the core wire 130, and terminate in a distal ball 134. In one embodiment, the core wire may have one or more tapers, and can extend proximally into tubular body 80. Other details regarding the core wire are discussed in assignee's copending application entitled CATHETER CORE WIRE, Serial No. 09/253,971, filed February 22, 1999, the entirety of which is hereby incorporated by reference.

In one embodiment, shown in **FIGURES 3A and 3B**, the tubular body 80 preferably has cuts 140 to create a coiled configuration. A sleeve 142 is preferably provided over the tubular body 80. Adhesive stops 144 and 146 are provided about 1-2 mm from the ends of the balloon, as described above, to control the wicking length of the adhesive 148 into the balloon working area. Balloon inflation is provided through the cuts

140 in the tubular body 80. A marker 150 is mounted to the tubular body 80 proximal of the balloon 72. Adhesive tapers 152A, 152B and 154 are provided adjacent the balloon 72 to provide a transition region between the tubular body 80 and balloon 72 at the balloon's proximal end 72A and between the balloon 72 and the core wire 328 at the balloon's distal end 72B. Other details regarding this balloon catheter may be found in assignee's above-referenced copending application FLEXIBLE CATHETER.

C. Introducer Arrangement

The catheter 70 and balloon 72 assembly preferably access the vascular site through a port in the patient obtained, for example, using an introducer arrangement 200, as depicted in **FIGURE 4**. As shown, a guide catheter 202 is inserted into a blood vessel 204 through an optional arterial sheath 206. The arterial sheath 206 is inserted into the blood vessel through the skin 208. A Y-adaptor 210 is connected to the proximal end of the guiding catheter 202. A hemostasis valve or a Touhy-Borst valve is installed within the Y-adaptor to prevent blood flow. A protective sheath assembly 212 accommodates the distal end of the catheter 70, including a surgical balloon 72, within the assembly. The protective sheath assembly 212 is then inserted into the Y-adaptor 210 with the distal end of the assembly 212 passing the hemostasis valve mounted in the Y-adaptor 210. As known in the art, the hemostasis valve maintains a tight seal around the protective sheath assembly 212 in order to prevent blood under arterial pressure from bleeding through the valve.

Referring also to **FIGURE 5**, the protective sheath assembly 212 has three major parts: a protective sheath 220, a female luer lock 222, and a strain-relief tubing 224. The protective sheath 220 has an elongated tubular body 226 defining an elongated lumen 230 along a longitudinal axis 232.

The lumen 230 can be further divided into two portions, the proximal portion 230b starting from the proximal end 234 and the distal portion 230a starting from the distal end 236 and extending over a relatively large part of the protective sheath 220.

The dimension of lumen 230 at the proximal portion 230b may vary depending on the outer diameter of the guidewire to be used. The inner diameter and the length of the proximal portion 230b of lumen 230 is designed so that the guidewire can be moved smoothly through the lumen 230 while providing a good seal between the guidewire and

the lumen 230 so as to prevent, or minimize, back flow of blood under arterial pressure. The dimension of the distal portion 230a of lumen 230, including the length and the inner diameter, may vary depending on the sizes of the balloon. However, the distal portion 230a should be large enough to accommodate and protect the balloon, as well as the soft tip of a balloon catheter, or other fixed wire devices.

FIGURE 6 illustrates a broken side cross-sectional view of the sheath assembly of **FIGURE 5** and further illustrates, in dotted lines, a catheter 70 positioned within the lumen 230 of the protective sheath 220. Specifically, the catheter 70 comprises a guidewire extending from the proximal end 234 of the sheath 220 and toward the distal end 236. The medical balloon 72, which is mounted on the distal end of the catheter 70, is housed protectively within the distal portion 230a of the sheath 220. It will be noted that the guidewire 70 is housed snugly in the proximal portion 230b of the lumen in order to prevent or at least minimize back blood flow under arterial pressure. The longitudinal position of the balloon is not particularly important so long as it is protectively contained within the lumen 230a.

In a method of the present invention, the proximal end of the guidewire is loaded into the sheath 220 beginning at the distal end 236. This loading is facilitated by a transition section 240, as illustrated in **FIGURE 5**, located between the distal section 230a and the proximal section 230b of the lumen 230. This lumen transition 240 between the proximal portion 230a and the distal portion 230b should be smooth to assist the loading of a balloon guidewire.

Further details and alternative preferred embodiments of introducer arrangements that may be used in conjunction with the present invention are described in assignee's co-pending U.S. application Serial No. 09/047303, filed on March 24, 1998, entitled MEDICAL WIRE INTRODUCER AND BALLOON PROTECTIVE SHEATH, which is hereby incorporated by reference in its entirety

D. Low Profile Catheter and Inflation Adapter

Referring again to **FIGURE 1**, the syringe assembly 50 is connected to the occlusion balloon guidewire catheter 70 utilizing an inflation adapter 54. The balloon guidewire catheter 70 has a side-access inflation port 90 and a low profile catheter valve 66 attached to its proximal end (see **FIGURES 7A and 7B**).

In one embodiment shown in **FIGURES 7A and 7B**, the low profile catheter valve 66 comprises a movable sealer portion 110 attached at a distal end of a wire segment 112 and positioned within the inflation lumen 86 of the guidewire catheter 70. The wire 112 may be secured to a spring just within a proximal opening of the catheter 70. It will be noted that various spring or biasing arrangements may be utilized, including a zig-zag wire 114 which is formed on or replaces the wire segment 112 and which provides biasing force to the sealer portion 110 due to frictional engagement with the walls of the lumen 86. The sealer portion 110 forms a fluid tight seal with the inflation lumen 86 by firmly contacting the entire circumference of a section of the inflation lumen 86. The sealer portion 110 may be positioned proximally of the side-access inflation port 90 on the catheter as shown in **FIGURE 7A**, to establish an unrestricted fluid pathway between the inflation port 90 and the inflatable balloon on the distal end. As desired, the clinician may move the sealer portion 110 to a position at or distal of the inflation port 90, as shown in **FIGURE 7B**, thereby preventing any fluid from being introduced into or withdrawn from the lumen 86 via the inflation port 90. The valve 66 is considered "low profile" because it is no larger in cross-sectional diameter than the catheter 70 itself. The low profile catheter valve 66 is described in more detail in the above-referenced application LOW PROFILE CATHETER VALVE AND INFLATION ADAPTER.

As discussed above with reference to **FIGURE 1**, the inflation port 90, proximal end of the catheter 70 and distal end of the valve 66 are positioned within the inflation adapter 54 (see **FIGURE 8**), to which the syringe assembly 50 is operably coupled via tubing 64. The syringe 60 is used to inject inflation fluid through the adapter 54 and valve 66 into the lumen 86 of the hollow catheter 70, and into the balloon 72. The inflation adapter 54 is used to open and close the valve 66 to regulate the inflation of the balloon 72.

Referring next to **FIGURE 8**, the inflation adapter 54 comprises a housing having two halves 94, 96 preferably formed of metal, medical grade polycarbonate, or the like. The halves 94, 96 are attached by hinges 98 to be separated or joined in a clam shell manner. A locking clip 100 secures the halves while the adapter 54 is in use. A groove 97 and clips 99 within the housing accept and securely hold the catheter 70 in a correct position. The male luer member 92 (**FIGURE 1**) or another suitable connector, extends

from a top of the housing to provide an inflation passageway. Seals 102 are provided within the housing and around an internal segment 104 of the inflation pathway to conduct the pressurized fluid provided by the syringe assembly 50.

An actuator 118, shown in **FIGURE 1** at the top of the adapter housing 94, controls a cam which operates sliding panels 120 (**FIGURE 8**) contained in the housing. Preferably, the catheter 70 is positioned within the housing with the valve closed (**FIGURE 7B**), such that the side inflation port 90 is located in the sealed inflation area 104 of the housing. The catheter 70 is then positioned in the second half 96 of the adapter 54. A distal portion of the catheter 70 extends out of the housing and into the patient, and a proximal portion of the catheter including the catheter valve 66 extends out of the other side of the adapter 54. The adapter is closed, the locking clip 100 is secured, and the syringe assembly 50 attached. The actuator 118 is moved from a first position to a second position, such that the sliding panels 120 within the housing cause the valve 66 to be in an open position to allow fluid flow through the inflation port 90 (**FIGURE 7A**). The syringe assembly 50 is then used to inflate the balloon 72. Closing the valve 66 is accomplished by moving the actuator 118 from the second position back to the first position (**FIGURE 7B**), such that the balloon inflation is maintained.

Other inflation adapter/inflation syringe assemblies may also be used. For instance, as shown in **FIGURE 9**, the sliding panels 120 and sealer portion 104 of the adapter 54 may be arranged somewhat differently than shown in **FIGURE 8**. Also, the adapter 54 can have additional features, such as a safety lock provided on the actuator knob 70 to prevent accidental opening when the adapter is being used and the catheter valve is open. In addition, the adapter can be provided with an overdrive system to overdrive a sealing member into a catheter. Details of these features and other inflation assemblies may be found in assignee's copending applications LOW PROFILE CATHETER VALVE AND INFLATION ADAPTER, referenced above, SYRINGE AND METHOD INFLATING LOW PROFILE CATHETER BALLOONS, Application Serial No. 09/025,991, filed February 19, 1998, and LOW VOLUME SYRINGE AND METHOD FOR INFLATING SURGICAL BALLOONS, Application Serial No. 09/195,796, filed November 19, 1998, all of which are incorporated by reference in their entirety.

Other connectors or fittings, such as tubing, quick connects and Y-connectors, may also be used in conjunction with an inflation/deflation device having features in accordance with the present invention according to the particular application and available supply of equipment, as shown. In **FIGURE 10**, for example, the inflation syringe 60 is connected via an injection cap 122 directly to the guidewire 70 to allow inflation of the balloon 72 on the catheter. In **FIGURE 11,** the inflation syringe 60 is connected via a short tubing 124 to a connector 126 which is in turn in fluid communication with the catheter 70. Thus, a variety of inflation devices and techniques are available in connection with the inflation syringe 60 of the present invention.

Further details regarding the occlusion system and its use are disclosed in assignee's copending applications entitled ASPIRATION CATHETER, Application Serial No. 09/026,013, filed February 19, 1998, and EXCHANGE METHOD FOR EMBOLI CONTAINMENT, Application Serial No. 09/049,712, filed March 27, 1998, both of which are hereby incorporated by reference in their entirety.

II. Low Volume Syringe

An embodiment of a low volume syringe 60 is shown schematically in **FIGURE 12**. The type or size illustrated is a 0.5 cc tuberculin syringe, although other size syringes having capacity ranging between about 0.02 cc to 1.0 cc may be used. More preferably, the capacity of the low volume syringe is between about 0.25 to 0.50 cc. The resultant displacement required for delivery of about 0.1 cc of fluid is about 10 mm for a 0.25 cc syringe. Indicia 164 may be provided along the length of the exterior surface of a cylinder 166 for visual aid of the clinician during use. Nevertheless, as described below in more detail, a mechanism is advantageously provided on the syringe 160 in order to accurately gauge the inflation fluid intake and expulsion as well as regulate the speed and pressure of fluid injection, thereby providing a means for the clinician to safely and accurately perform the desired procedure.

Referring to **FIGURES 12** and **13**, the cylindrical body 166 of the syringe 160 comprises a stop or flange 168 extending radially outward at a proximal end and preferably being attached at a distal end to an injection cap 170. The distal end of the cylinder 166 has a nose portion 172 with a reduced diameter for connection with the injection cap 170. A plunger 174 has a shaft 176 of appropriate length and a resilient

piston 178 attached at its distal end. The shaft 176 is inserted in a central lumen 179 of the cylinder and the piston 178 provides sealing engagement with the inner surface of the cylinder 166. The plunger 174 has a disk 58 at the proximal end of the shaft 176 for operation of the plunger 174. A preferred source for unmodified, conventional syringes is Becton Dickinson & Co. of Franklin Lakes, New Jersey.

The injection cap 170 preferably comprises a modified female member of a luer type connector. A first end 182 of the cap has a proximal wall with an aperture corresponding to the outer diameter of the cylinder 166, and a distal wall having an aperture corresponding to the outer diameter of the nose 172. These apertures are used to mount the injection cap 170 on the syringe 60. A threaded second end 184 of the cap can be screwed onto a male luer member, as in the example of **FIGURE 1**. Alternatively, a tubular segment 188 within the second end 184 of the cap may be directly attached to the control end of the guidewire 70 using a sleeve 190, as with **FIGURE 10**. Other suitable cap configurations may also be used to facilitate coupling of the syringe to a guidewire or catheter to provide inflation of the balloon. One preferred source of the cap is Medical Disposables International, Inc. of West Conshohocken, Pennsylvania.

Another preferred embodiment of the low volume syringe is shown in **FIGURES 14-18**. The low-volume syringe 260 preferably has a capacity ranging between about 0.1 cc and about 10 cc, and more preferably a capacity between about 0.2 cc and about 2 cc. The syringe 260 includes an elongated hollow body or barrel 264 which is preferably generally cylindrical, but the body can have any desired shape or cross-section. The body 264 has a distal end 268 with an attachment portion 270 which can be connected to various medical components such as a catheter. The attachment portion 270, for example, may include a nose 272, an injection cap 274 and internal threads 276, but it will be understood that the attachment portion can include any type of known connector to attach the syringe 260 to various types of medical components or instruments. The body 264 also includes a proximal end 280 with a flange 282 and an opening 284. The opening 284 is preferably circular and generally aligned with a longitudinal axis extending through the center of the body 264. The stop 282 also includes a radially outwardly extending annular ridge 288. The ridge 288 preferably extends outwardly about 1/16 of an inch from the

body 264 and the ridge preferably has a length of about 1/4 of an inch, but the ridge can have any desired dimensions and configuration.

With continued reference to **FIGURES 14-18**, the syringe 260 includes a plunger 290 which is sized and dimensioned to be at least partially positioned within the elongated body 264. The plunger 290 includes an elongated shaft 292 which is generally circular in cross-section and is preferably constructed from material such as plastic and composites. The plunger 290 includes a distal end 294 which is positioned near the distal end 268 of the body 264 and a proximal end 296 which is positioned near the proximal end 280 of the body. The distal end 294 of the plunger 290 includes a piston 300 with a center section 302 and two outwardly extending annular flanges 304 and 306, respectively. The annular flanges 304 and 306 extend outwardly and slidably engage the inner wall of the elongated body 264 to create a fluid-tight seal with the elongated body. The piston 300 is preferably constructed from a resilient material such as rubber, but it can be constructed from any material which is suitable for its intended purpose. It will be understood that the piston 300 may have any desired size and/or configuration.

The plunger shaft 292 is generally cylindrical and has an annular notch 310 formed therein at a distance from the piston 300 of the shaft. A C-clip 312 is adapted to fit into the notch 310 and is sized to extend annularly outwardly from the shaft 292, effectively creating a ridge encircling the shaft. A length of the shaft near the proximal end is split into two shaft legs 314, 316. A collapsible chamber 320 is defined between the legs 314, 316. Threads 322 are formed about the outer circumference of the legs 314, 316.

A hollow plunger guide 324 has a neck portion 326 formed at its distal end and is adapted to fit complementarily into the proximal opening 284 of the body. The plunger guide 324 is generally cylindrical and has threads 328 formed on its inner surface. The inner threads 328 of the plunger guide 324 are adapted to engage the outer threads 322 of the plunger legs 314, 316 so that the plunger 290 may be threaded within the plunger guide 324. As the plunger 290 is rotated, the threads 322, 328 interact to advance or retract the plunger 290 within the syringe body, depending on the direction of rotation. The inner diameter of the hollow plunger guide's distal neck 326 is less than the diameter of the plunger's clip 312. As such, the C-clip 312 cannot fit through the plunger guide

neck 326. Instead, retraction of the plunger 290 from the barrel 264 is stopped when the C-clip 312 contacts the plunger neck portion 326.

Continuing with **FIGURES 14-18**, the proximal end 296 of the plunger 290 includes a handle 330 comprising a generally circular disk 332 that is mounted to the end of the shaft 292. The disk 332 preferably has ridges 334 formed along an edge thereof, a diameter of about 1 inch, and a thickness of about 1/8 of an inch so that the clinician can easily grasp and rotate the handle 330. However, the disk 332 can be larger or smaller and it can have any desired shape such as square, rectangular, triangular, etc.

A plunger actuator 340 comprises a shaft 342 with a head 344 formed at its distal end and a tab 346 formed at its proximal end. The plunger actuator shaft 342 is adapted to fit through a hole 348 formed in the handle 330 of the plunger 290 and the head 344 is positioned within the collapsible chamber 320. A spring 350 is disposed within the collapsible chamber 320 between the plunger actuator head 344 and a distal end 352 of the collapsible chamber 320. The spring 350 biases the plunger actuator 340 in a proximal direction. The plunger actuator shaft 342 includes an annular protrusion 354 which contacts the plunger handle 330 to stop the plunger actuator 340 from being pushed by the spring 350 out of the collapsible chamber 320. Thus, the head 344 of the plunger actuator 340 is biased by the spring 350 into a position between the legs 314, 316 of the collapsible chamber 320 about medially between the chamber's proximal and distal ends, as shown in **FIGURES 15 and 16**. In this position, the head 344 prevents the opposing legs 314, 316 from collapsing toward each other. Thus, the chamber 320 is held in an "open" position.

With particular reference to **FIGURES 15 AND 16,** when the collapsible chamber 320 is held open by the plunger actuator head 344, the chamber outer threads 322 engage the inner threads 328 of the plunger guide 324. Thus, the plunger 290 can be linearly moved relative to the barrel 264 only by rotating the handle 330. When the handle 330 is rotated in the clockwise direction, the plunger 290 preferably moves toward the distal end 268 of the barrel 264, thus ejecting the contents of the barrel 264 and inflating an associated surgical balloon. When the plunger 290 is rotated in the counterclockwise direction, the plunger 290 is preferably retracted into the barrel 264, thus deflating the balloon.

When the plunger actuator tab 346 is pushed, the plunger actuator 340 compresses the spring 350 and moves the head 344 out of supportive contact with the collapsible chamber legs 314, 316. Thus, as shown in **FIGURES 17 and 18**, the chamber legs 314, 316 collapse toward each other and the chamber's outer threads 322 move out of engagement with the plunger guide inner threads 328. In this condition, the plunger 290 may be linearly moved relative to the barrel 264 by simply pushing or pulling the handle 330 in the same manner as conventional plungers.

In use, the syringe 260 is preferably first oriented in the open position and the plunger 290 is retracted as shown in **FIGURE 15**. The hollow body 264 between the distal end 268 and the piston 300 is preferably filled with inflation fluid. The handle 330 is then rotated, thus advancing the plunger 290 and delivering the fluid in a regulated, pressure-controlled manner. When the fluid is fully delivered, the syringe 260 is in the position depicted in **FIGURE 16** and the surgical balloon is inflated

To quickly deflate the balloon, the plunger actuator 340 is depressed, allowing the chamber 320 to collapse as shown in **FIGURE 17**. While the plunger actuator 340 remains depressed, the clinician pulls on the handle 330, slidably retracting the plunger 290 as shown in **FIGURE 18**.

FIGURES 19 and 20 show a preferred embodiment of an integrated inflation/deflation syringe 260a having a variable cross-section barrel 264a. The syringe shares many similarities with the embodiment just discussed and shown in **FIGURES 14-18**. Thus, similar parts have been assigned the same numbers used above, but including the appellation "a." The similar parts function in substantially the same manner as described above.

With reference to **FIGURES 19 and 20**, the variable cross-section barrel 264a has a large diameter portion 265 and a small diameter portion 266. The large diameter portion 265 has a cross-section about the same as that of a standard 30-60 cc syringe. The small diameter portion 266 has a cross-section about the same as the low-volume syringe barrel 264 of **FIGURES 14-18**. The plunger 290a is sized and adapted to slidably fit within the large diameter portion 265 and the piston 300a is sized adapted to effect a seal with the inner surface of the barrel 264a in the large diameter portion 265.

The inflation/deflation syringe 260a is adapted to operate in the same manner as the syringe 260 described above and shown in **FIGURES 14-18**. Namely, a plunger actuator head 344a supports a collapsible chamber 320a to engage threads 322a on a chamber outer surface with threads 328a on a plunger guide 324a inner surface. The plunger 290a is thus advanced distally within the barrel 264a by rotating a plunger handle 330. Indicia 267 marked on the outside surface of the small diameter section 266 allow the clinician to precisely gauge the volume of liquid delivered by the syringe 260a and the rotational advancement facilitates slow, regulated fluid delivery despite the relatively large size of the barrel 264a in the large diameter portion 265. When the plunger actuator 340a is depressed, moving the head 344a out of supporting contact with the chamber legs 314a, 316a, the chamber 320a collapses. The threads 322a, 328a thus disengage and the piston 300a is free to slide linearly within the barrel 264a. Thus, the plunger 290a may be pulled proximally, rapidly deflating an associated balloon. Because of the relatively large size of the large diameter barrel section 265, the syringe 260a provides powerful evacuation force.

With next reference to **FIGURES 21-27**, another preferred embodiment of a precision syringe 360 having features in accordance with the present invention is disclosed. With first reference to **FIGURE 21**, the syringe 360 includes a body 364 comprising an elongated hollow barrel 366, a lock body 368, and a correspondingly hollow plunger guide 370. A lumen 372 is defined extending through the hollow body 364 and is preferably circular and generally aligned with a longitudinal axis extending through the center of the body 364. The barrel 366 preferably has a capacity ranging between about 0.1 cc and about 10 cc, and more preferably a capacity between about 0.2 cc and about 2 cc, and has a distal end 378 with an attachment portion 380 which can be connected to various medical components such as a catheter. Referring particularly to **FIGURES 22 and 23**, the attachment portion 380, for example, may include a nose 382, an injection cap 384 and internal threads 386, but it will be understood that the attachment portion can include any other type of known connector to attach the syringe 360 to various types of medical components or instruments.

Referring again primarily to **FIGURES 21-23**, a proximal end 390 of the barrel 366 is attached to a distal side 392 of the lock body 368. A proximal side 394 of the lock

body 368 is coupled to a distal end 396 of the plunger guide 370, which has a proximal end 398 with a flange or stop 400 formed thereon. The stop 400 includes a radially outwardly extending annular ridge. The ridge preferably extends outwardly about 1/16 of an inch from the body 364 and the ridge preferably has a length of about 1/8 of an inch, but the ridge can have any desired dimensions and configuration.

The syringe 360 also includes a plunger 404 which is sized and dimensioned to be at least partially positioned within the hollow body 364. The plunger 404 includes an elongated shaft 406 which is generally circular in cross-section and is preferably constructed from material such as plastic, metal or composites. The plunger 404 is adapted to fit through the plunger guide 370 and into the barrel 366 and includes a distal end 408 which is positioned near the distal end 378 of the barrel, and a proximal end 410 which is positioned near the proximal end 398 of the plunger guide 370 as shown in **FIGURES 21 and 23**. The distal end 408 of the plunger 404 includes a piston 414 which is adapted to form a seal between the piston 414 and the inner surface of the barrel 366, as above. The plunger shaft 406 is threaded 416 from a point near the distal end 408 to a plunger stop 418. The stop 418 comprises an annular ridge extending outwardly about 1/16 inch from the shaft. A guide ring 420 within the plunger guide 370 helps stabilize the plunger 404 within the guide. As shown in **FIGURE 19**, the stop 418 on the plunger 404 contacts the plunger guide flange 400 to prevent further distal advancement of the plunger 404.

Referring again to **FIGURE 21**, the proximal end 410 of the plunger 404 includes a handle 422 comprising a generally circular knob 424 with ridges 426 formed around the perimeter thereof to facilitate rotational grip by the clinician. The knob 424 preferably has a diameter of about 1 inch and a thickness of about 1/8 of an inch so that the clinician can easily grasp it, but the knob can be larger or smaller and it can have any desired shape such as square, rectangular, triangular, etc.

With further reference to **FIGURES 24 and 25**, the lock body 368 has a slot 430 which is adapted to receive a locker tab 432 therein. A hole 434 extends through the locker tab 432 and has an upper portion 436 and a lower portion 438. The radius of curvature of the upper portion 436 is larger than that of the lower portion 438, which is threaded 439 (see **FIGURE 21**) to match the threads 416 on the plunger 404. A spring

440 such as a parabolic spring or coiled spring is disposed in the lock body slot 430 in contact with a curved leading edge 442 of the tab 432 and biases the locker tab 432 away from the spring 440. When the plunger 404 is inserted into the syringe body 364, the spring 440 biases the locker hole threads 439 into contact with the plunger threads 416, as shown in **FIGURES 22-24**. Thus, to advance or retract the plunger 404, the knob 424 must be rotated so that the plunger 404 is threaded into or out of the body 364. In this manner, precise volumes of liquid may be delivered out of the plunger barrel 366 in a regulated, relatively slow manner. Thus, build-up of excessive pressure in the occlusion system will be avoided because the plunger 404 will not be advanced too quickly down the barrel 366 when ejecting the barrel's contents.

When a back edge 444 of the locker tab 432 is depressed, as shown in **FIGURES 25-27**, the locker threads 439 are taken out of engagement with the plunger threads 416. The plunger 404 is thus free to be slidably moved without resistance from threads. Thus, the plunger knob 424 can be pushed or pulled to rapidly slide the plunger 404 within the barrel 366. This arrangement is especially desirable to enable quick deflation of an occlusion balloon.

The above preferred embodiment enables precise regulated injection of liquid when the plunger 404 is rotated, thus delivering the contents of the barrel 366 slowly and avoiding over pressurizing a connected occlusion system. However, when the lock tab 432 is depressed, the syringe 360 allows rapid deflation of the associated balloon.

FIGURES 28-32 show another preferred embodiment of a syringe 460 having features in accordance with the present invention. The syringe 460 is adapted to inflate an occlusion balloon by delivering precise volume of liquid in a regulated, low pressure manner that will not cause leaks in a system and also to deflate the occlusion balloon quickly.

With reference first to **FIGURE 28**, the syringe 460 comprises a hollow body 464 with a barrel 466 extending from a distal end 468 of the body 464. The majority of the body 464 has a greater diameter than the barrel 466, which preferably has a capacity between about 0.1 cc and 10 cc, and more preferably between about 0.2 cc and 2 cc. The barrel 466 has a distal end 469 with an attachment portion 470 which can be connected to various medical components such as a catheter. The attachment portion 470 may include,

for example, a nose 472, an injection cap, and internal threads, but it will be understood that the attachment portion can include any type of known connector to attach the syringe 460 to various types of medical components or instruments.

A plunger 480 is disposed within the body 464 and barrel 466 and comprises a shaft 482 with a piston 484 attached to a distal end thereof. The piston 484 is adapted to form a seal between the piston 484 and the inner surface of the barrel 466, as above. A shuttle 490 is attached to a proximal end 492 of the plunger shaft 482 and is slidably disposed within the main body 464. With further reference to **FIGURE 29**, the shuttle 490 has a chamber 494 formed therewithin and an opening 496 to the chamber 494 is formed at a proximal end 498 of the shuttle 490. The chamber 494 is preferably substantially cylindrical and has a proximal neck portion 500 surrounding the opening 496 and having a diameter less than the diameter of the majority of the chamber 494.

Referring again to **FIGURES 28-31**, a plunger actuator 502 is provided which comprises a shaft 504 having a distal end 506 which is disposed in the shuttle chamber 494 and a proximal end 508 which extends out of a proximal end 510 of the body 464 and on which a handle 512 is formed. The handle 512 preferably comprises a generally circular disk 514 with a diameter of about 7/8 of an inch and a thickness of about 1/8 of an inch so that the clinician can easily grasp it. However, the disk can be larger or smaller and it can have any desired shape.

An annular stop ridge 518 is formed on the distal end 506 of the plunger actuator 502. The ridge 518 is sized and adapted to slide freely within the chamber 494, but has a diameter greater than that of the chamber neck 500 and will not fit through the opening 496. Therefore, the stop ridge 518 prevents the plunger actuator 502 from being completely removed from the shuttle chamber 494.

The proximal end 498 of the shuttle 490 has a flat surface on which a distal end 520 of a coil spring 522 rests. The spring 522 encircles the plunger actuator shaft 504 and extends proximally to a spring stop ridge 524 which protrudes annularly from the shaft 504.

Referring more particularly to **FIGURES 28 and 30**, the proximal end 510 of the body 464 has a flange 526 formed thereon. A hollow detent cylinder 530 extends longitudinally from the body flange 526. A cover 532 is disposed on a proximal end of

the detent cylinder 530 and has an opening 536 formed therethrough. A detent mechanism 540 is disposed within the detent cylinder 530. With further reference to **FIGURE 32**, the detent mechanism 540 preferably comprises opposing tabs 542, 543 linearly movable in a direction generally perpendicular to the body 464 and biased toward each other by springs 544, 545. A cavity 546, 547 is formed in each tab 542, 543, respectively, and is adapted to closely surround the plunger actuator shaft 504. With reference to **FIGURES 28 and 30**, a detent ridge 548 protrudes annularly from the plunger actuator shaft 504 between the spring stop 524 and the handle 512. A distal surface 550 of the detent ridge 548 is preferably sloped at about a 45° angle relative to the detent tabs 542, 543. The sloped distal surface 550 is adapted to deflect the detent tabs 542, 543 when the detent ridge 548 passes between them, thereby facilitating easy passage of the detent ridge 548 through the detent mechanism 540. A proximal surface 552 of the detent ridge 548 is also sloped, preferably at an angle relative to the detent tabs 542, 543 of about 15-40° and most preferably about 30°. The sloped proximal surface 552 is also adapted to deflect the tabs 542, 543 to facilitate passage of the detent ridge 548 through the detent mechanism 540, but due to the slope angle, significantly more force is required to move the detent ridge 548 proximally through the tabs than distally through the tabs.

This arrangement is particularly useful when operating the syringe 460. As shown in **FIGURE 30**, when the disk 514 is pushed downward so that the detent ridge 548 passes through the detent mechanism 540, the spring 522 is compressed against the shuttle 490 and the distal end 506 of the plunger actuator 502 approaches a distal end 554 of the shuttle chamber 494. When compressed, the spring 522 exerts a reaction force F on the spring lock 524 and the shuttle 490. The spring 522 is adapted to not generate enough spring force F to push the detent ridge 548 proximally through the detent mechanism 540. Therefore, the spring force F instead tends to move the shuttle 490 in a distal direction, thus advancing the plunger 480 toward the barrel's distal end 469 until the contents of the barrel 466 are delivered and the spring 522 is relaxed, as shown in **FIGURE 31**.

An advantage of the present embodiment is regulation of pressure build-up in the occlusion system. As discussed above, when liquid is injected too quickly into the

system, pressure may build to very high levels and cause leaks in the system. The present embodiment allows a clinician to not worry about the rate of entry of liquid into the system. Instead, the clinician simply depresses the tab 514 until the detent ridge 548 is engaged with the detent mechanism 540. The spring 522 is thus compressed as shown in **FIGURE 30**. As discussed above, the spring exerts force F to move the shuttle 490 and plunger 480 distally within the body 464, delivering the contents of the barrels 466 to the occlusion system. However, the spring 522 is chosen to have a spring constant adapted to exert a force less than the pressure that would cause a leak in the system. Thus, the spring 522 will inherently regulate system pressure during fluid delivery.

To deflate the occlusion balloon, the clinician pulls the plunger actuator 502 proximally, preferably moving the plunger 480 from the position depicted in **FIGURE 27** to the position shown in **FIGURE 25**. The pulling force of the clinician is sufficient to move the detent ridge 548 through the detent mechanism 540 and the plunger actuator stop ridge 518 contacts the shuttle neck 500 so that the shuttle 490, and thus the plunger 480, moves proximally with the plunger actuator 502. Thus, the contents of the catheter are drawn into the barrel 466 and the balloon is deflated quickly

III. Inflation Syringe and Balloon Sizing System

To accommodate a variety of vessel sizes, various sizes of occlusion balloons are typically used. For example, balloon diameters of 3.0 mm, 3.5 mm, 4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, and 6.0 mm are common. Balloons with diameters of 2.0 mm, 2.5 mm and 7.0 mm are also useful. Prior systems required different inflation devices to be used in combination with each of the balloon sizes. Further details are provided in the above-referenced copending application SYRINGE AND METHOD FOR INFLATING LOW VOLUME CATHETER BALLOONS. Improvements in balloon technology have resulted in at least one system in which a single balloon is suitable for use in a number of different vessel diameters. These improvements are disclosed in the above-referenced copending U.S. Application BALLOON CATHETER AND METHOD OF MANUFACTURE.

A single syringe may be used to provide inflation fluid to the balloon. If desired, the syringe may be marked with indicia along its barrel to assist the physician during

inflation of the balloon. The indicia are adapted to enable precise delivery of low volumes of fluid, but also versatile enough to enable accurate delivery of a range of volumes. For example, a 2.0 mm diameter balloon may be able to accommodate only about 0.01 cc of inflation fluid and a 7.0 mm balloon may require about 0.25 cc of fluid

IV. Syringe Assembly

In the embodiment of **FIGURE 1**, an inflation syringe 60 is depicted used in an assembly 50 including a conventional high capacity or reservoir syringe 62. The reservoir syringe 62 provides the desirable power and volume for quickly priming the balloon 72 and guidewire 70, as well as for quickly deflating the balloon 72 for withdrawal from the patient. However, it will be noted that the inflation syringe 60 can be utilized in combination with other reservoir systems, of which the assembly 50 is only one example. Also, any of the preferred syringe embodiments disclosed above can be utilized in combination with such a reservoir syringe 62 or other reservoir systems.

An alternative syringe assembly is shown in **FIGURE 33**, wherein a conventional four-way manifold 600 is attached to a reservoir syringe 602 and a y-connection 604 is attached to the proximal end of a catheter 610. The manifold 600 provides a pressure monitoring line 612, a dye supply line 614, a saline supply line 616, and a waste removal line 618. Proximal this first connection 604, another y-connection 620 couples a low volume syringe 630 with a guidewire 632 and, thus, with the manifold 600 and reservoir syringe 602. The syringe 630 is used to inflate the distal balloon 636 on guidewire 632. Although the use of a manifold 600 is typically reserved for procedures using larger or therapeutic balloons, those skilled in the art will appreciate that the present invention is readily adapted for use with this more elaborate system.

As understood by those skilled in the art, the assembly in the present invention is not limited to the embodiments discussed herein, and may be included with other adapters, manifolds, and/or connectors, as desired. That is, advantages realized from the use of the low volume syringe with the higher volume syringe for deflation and inflation of a balloon during various procedures is not limited to their particular connections or additional apparatus.

Another preferred embodiment of a syringe assembly 650 for inflation and deflation of an occlusion balloon is shown in **FIGURES 34-44**. With first reference to

FIGURE 34, the syringe assembly 650 comprises a low-volume inflation syringe 660 and a high capacity or reservoir syringe 662 encased together in a housing 664. Like the syringe assembly 50 shown in **FIGURE 1**, and as illustrated in **FIGURE 35**, the syringe assembly 650 is preferably attached via a connector 666 and a short tube 668 to an adapter 54 within which a low profile catheter valve 66 and a balloon catheter 70 are engaged during use.

FIGURE 36 illustrates the present syringe assembly 650 without its housing 664. As shown, the inflation and reservoir syringes 660, 662 are preferably oriented side-by-side and in communication with each other through a channel 680.

With continued reference to **FIGURE 36**, the inflation syringe 660 preferably has a capacity ranging between about 0.02 cc and 2 cc. The syringe 660 includes a hollow barrel 682 having an open proximal end 684 and a distal end 686 with an attachment portion 688 which can be connected to various medical components, such as a catheter, in any known manner. A port 690 is formed through the side of the barrel 682 between the proximal 684 and distal 686 ends.

The syringe 660 also includes a plunger 692 longitudinally slidable within the barrel 682 and sized and dimensioned to be at least partially positioned within the barrel 682. The plunger 692 includes an elongate shaft 694 with a distal end 696 and a proximal end 698. A piston 699 is disposed on the distal end 696 and is adapted to form a seal between the piston 699 and the inner surface of the barrel 682. The proximal end 698 of the plunger shaft 694 is preferably attached to a gear rack 700 having a plurality of gear teeth or ridges 702 formed thereon. Preferably, the gear pitch is about 48 and the gear rack 700 is about 1/8" thick. The gear rack 700 is preferably formed of modified molded nylon and alternatively could be formed of stainless steel.

The reservoir syringe 662 provides desirable power and volume for quickly priming the balloon and catheter. It is preferably of any conventional large volume syringe type with a capacity of between about 10-50 cc and more preferably about 40 cc. As shown in **FIGURE 36**, the reservoir syringe 662 preferably has a generally cylindrical hollow barrel 710 having an open proximal end 712 and a tapered distal end 714. The tapered distal end 714 of the barrel 710 opens into the channel 680, which leads to the inflation syringe port 690.

The reservoir syringe 662 also includes a plunger 716 which is sized and dimensioned to be at least partially positioned within the hollow barrel 710. The plunger 716 includes an elongated shaft 718 which is generally circular in cross-section and is preferably constructed from material such as plastic or composites. A distal end 720 of the plunger shaft 718 includes a piston 722 which is adapted to form a seal between the piston 722 and the inner surface of the barrel 710. A handle 730 is formed at a proximal end 732 of the plunger 716. Preferably, the handle 730 is large, as illustrated in **FIGURES 34-43**, and is easily held in a clinician's hand.

With next reference to **FIGURES 37-42**, the housing 664 preferably comprises a right half 740 and a left half 742 attached by screws, bolts, a sonic weld, or other means. The housing 664 is adapted to fit around the syringe assembly 650. With particular reference to **FIGURES 41 and 42**, each housing half 740, 742 has a large cavity 744 and a small cavity 746 to accommodate the large and small syringe barrels 710, 682, respectively. Each housing half 740, 742 further includes a channel cavity 748 and gear rack cavity 750 to accommodate the channel 680 and gear rack 700, respectively. **FIGURE 43** depicts the syringe assembly 650 disposed in a housing half 740.

With reference again to **FIGURES 37-42**, a large window 752 is formed through each housing half to allow the clinician to view the contents of the large syringe barrel 710. Similarly, a cutout 754 is formed in each housing half to allow the clinician to view the contents of the inflation syringe barrel 682.

An inflation/deflation knob 760 is disposed on the outside of the housing 664. The inflation knob 760 is preferably formed of Delrin plastic but may also be preferably formed of metal or other plastics such as polycarbonate or ABS. With particular reference to **FIGURES 43 and 44**, the knob 760 is connected to a spur gear 762 having a pitch of about 48 and a pitch diameter of preferably about .292 inches. The spur gear 762 is adapted to engagingly mate the gear rack 700 attached to the inflation syringe 660. The teeth 764 of the spur gear 762, as shown in **FIGURE 44**, communicate with the gear rack 700. Thus, when the knob 760 is rotated, the rotating spur gear 762 linearly moves the rack 700, thus advancing or retracting the plunger 692 within the inflation syringe barrel 682.

Referring again to **FIGURE 37**, indicia 770 are preferably located on the housing 664 adjacent the knob 760 so that a clinician using the device can monitor the precise volume of liquid delivered by the inflation syringe 660. As depicted, the indicia 770 preferably comprise numbers corresponding to the size and shape of balloon used. When the knob 760 is rotated from the "DEFLATE" or "0" position to the number corresponding to the balloon in use, the syringe assembly 650 delivers the fluid volume associated with that balloon size. Alternatively, the indicia 770 could indicate the standard or metric volume of fluid delivered at each position.

To use the device, the inflation syringe plunger piston 699 is preferably first disposed immediately adjacent the proximal side of the port 690, as depicted in **FIGURES 36 and 43**. The knob 760 is positioned to correspond with the legend "DEFLATE" or "0" as indicated on the housing. The clinician connects the syringe assembly connector 666 to a source of balloon inflation fluid, preferably a diluted heparinized saline/contrast mixture, and retracts the large plunger 716 to fill the assembly 650 with 10-15 cc of fluid. Air is next purged from the syringe assembly 650 by holding the device vertically with the tip 686 pointing up and flushing air and air bubbles out by depressing the reservoir plunger 716. Excess fluid is flushed out, leaving about 5-10 cc of fluid.

The syringe assembly 650 is next connected to the occlusion catheter 70, preferably through an adapter 54 such as discussed above. The reservoir plunger 716 is then further retracted to prime the catheter. When priming, the reservoir plunger 716 is preferably held fully retracted for about 30 seconds until substantial all air within the catheter 70 has been aspirated. When the air is aspirated, the plunger 716 is slowly released to a neutral position.

When priming is complete and the surgical balloon is positioned as desired in the patient, the clinician rotates the knob 760 from the "DEFLATE" position to the desired setting corresponding to the balloon size and shape being used. Rotating the knob 760 moves the inflation syringe plunger 692 linearly towards the distal end 686 of the inflation syringe barrel 682, thus delivering inflation fluid to the balloon 72. To deflate the balloon, the knob 760 is rotated back to the "DEFLATE" position, thus linearly retracting the plunger 692 and drawing the inflation liquid back into the inflation syringe barrel 682.

With next reference to **FIGURE 45**, an exploded perspective view of another embodiment of a syringe assembly 800 is disclosed. Syringe assembly 800 is similar in construction and operation to the syringe assembly 650 just discussed. Since syringe assembly 800 shares many similarities with the above syringe assembly 650, similar parts share part numbers; however, parts associated with syringe assembly 800 include the appellation "a."

Referring next to **FIGURE 46**, a knob assembly 802 is disclosed for use with the syringe assembly 800. The knob assembly 802 includes a knob plate 804 with an access hole 806 formed therethrough and a detent ring 808 encircling the hole 806. Indicia 770a are printed on the knob plate 804 adjacent the detent ring 808. At least two rods 810 depend from the knob 760a and are adapted to extend through the hole 806. Referring back to **FIGURE 45**, the right and left halves 740a, 742a of the syringe assembly housing 664a each have a shallow cavity 812 formed in an upper portion. The cavity 812 is adapted to receive the knob plate 804 complementarily therewithin, as shown in **FIGURE 47** and **48**. Referring back to **FIGURES 45** and **46**, the rods 810 extend through the knob plate hole 806 to interact with a gear rack 700a which is attached to an inflation plunger 692a. As shown more particularly in **FIGURES 45** and **49**, the gear rack 700a preferably comprises a series of channels 814 sized and adapted to accept the rods 810 therein. The channels 814 and rods 810 are further adapted so that when the knob 760a is rotated, correspondingly moving the rods 810, the rods 810 move within the channels 814 and engage the channel walls 816 to advance or retract the attached inflation syringe plunger 692a.

Referring back to **FIGURE 46**, the knob 760a has a detent hole (not shown) into which a spring 820 is placed. A ball 822 is placed in the hole with the spring 820. When the knob 760a is installed into the knob plate 804, the ball 822 is urged into contact with the detent ring 808. Cavities 824 are formed in the detent ring 808, each cavity 824 adjacent to a corresponding indicia mark 770a which, in turn, corresponds to a particular balloon size. Thus, as the knob 760a is rotated to any delineated indicia location, the spring 820 forces the ball 822 into the accompanying cavity 824, effectuating a detent.

Referring back to **FIGURE 45**, the syringe assembly 800 includes an inflation barrel 682a having a relatively low volume, preferably between about .02 cc - 1.0 cc. The

inflation barrel 682a preferably comprises a distal portion 828, medial portion 830, and proximal portion 832 mated together. Referring also to **FIGURES 47** and **50**, the medial portion 830 includes a port 690a which connects to the channel 680a between the reservoir syringe barrel 710a and the inflation barrel 682a. The distal portion 828 and proximal portion 832 each have a mating member 834 which fits complementarily into cavities formed in the medial portion 830, thus defining a continuous lumen 838 through the barrel 682a.

Referring next to **FIGURE 49**, the inflation plunger 692a extending from the gear rack 700a preferably comprises a substantially cylindrical precision-milled stainless steel rod. With reference also to **FIGURE 50**, the barrel 682a has a capacity ranging from between about .02 cc to 1.0 cc and most preferably between about .25 cc to .50 cc. The plunger 692a is adapted to slide freely within the barrel 682a. The medial portion 830 of the inflation barrel 682a preferably includes a pair of O-ring seals 840, one disposed on either side of the port 690a. The O-rings 840 are preferably sized to effect a seal with the inflation plunger 692a. In operation, when the inflation plunger 692a is advanced within the barrel 682a through the O-ring seals 840, the plunger displaces fluid within the barrel lumen 838. The displaced fluid is forced out of the barrel 682a through the distal end 686a, and is thus delivered to an attached balloon catheter. Since delivery of fluid is determined by the volume displaced by the plunger 692a, very small volumes may be precisely delivered without requiring the syringe barrel 682a to have a very small inner diameter that would require expensive manufacturing.

Thus, certain advantages of the embodiment of the present invention shown in **FIGURES 47** and **50** are evident. In one aspect of this embodiment, the piston 834, as it is moved distally (or to the left in **FIGURES 47** and **50**) serves to seal the port 690a, thereby shutting off any access to the volumetric capacity of the reservoir syringe barrel 710a. In effect, then, this configuration eliminates the need or use of a stopcock which would typically be utilized in a two-separate-syringe embodiment. Accordingly, in this embodiment of the present invention, there is provided an automatic valve for communication with either the inflation barrel 682a or the reservoir syringe barrel 710a.

In another aspect of this embodiment, the inflation barrel 682a is situated so as to be distally oriented with respect to the reservoir syringe barrel 710a. This arrangement

facilitates the automatic valve or sealing mechanism described in the previous paragraph, while still providing a long range of travel for the plunger 692a of the reservoir syringe barrel 710a.

Moreover, as best illustrated in **FIGURE 50**, this longer range of travel, coupled with a minimized diameter of the plunger 692a of the inflation barrel 682a, provides for a very accurate syringe, in the sense that it is able to deliver very accurate and small volumes of fluid such as .05 cc, etc. This is achieved, in part, by fixing the O-ring seal 840, shown in **FIGURE 50**, and allowing only the plunger 692a to pass through the O-ring 840. This means that the pressure of the inflation barrel 682a is determined by the diameter of the plunger and not by the entire outer diameter of the barrel 682a. In other words, if the O-ring were to move with the plunger 692a, the pressure, and therefore the volume of fluid delivered, would vary with the entire inner diameter of the inflation barrel 682a. With a smaller diameter plunger and a fixed O-ring, the smaller cross-sectional surface area defined by the diameter of the plunger allows the plunger to travel a greater distance while still delivering a smaller, accurate volume of fluid. Accordingly, it is easier to manufacture and to hold tolerances relative to a plunger rather than the inner diameter of a barrel or syringe.

With reference next to **FIGURE 51**, the reservoir syringe plunger 716a preferably has a main body 842 with two substantially flat opposing surfaces 844 and two arcuate opposing surfaces 846. A cylindrical distal portion 848 extends from a distal end of the main body 842. The distal cylinder 848 has a diameter substantially equal to the distance between the opposing flat surface 844; the diametrical distance between the arcuate surfaces 846 is greater than the distal cylinder 848 diameter. Thus, a distal notch 850 is defined between each arcuate surface 846 and the distal cylinder 848 surface.

Referring next to **FIGURES 45** and **46**, the housing 664a is adapted to complementarily receive the plunger main body 842. Specifically, the housing 664a has flat sides 852 which are complementary to the flat surfaces 844 of the main body, and arcuate sides 854 which complement the arcuate surfaces 846 of the plunger. This construction allows the plunger 746a to slide within the housing 664a, but not to rotate. A lock notch 856 is formed at the proximal end of the housing 664a. When the plunger 716a is retracted from the reservoir barrel 710a so that the plunger distal notch 850 is proximal

the housing lock notch 856, the plunger main body 842 is free of the housing and the plunger may be rotated. When the plunger 716a is rotated about one-quarter turn, the plunger notch 850 will engage the housing lock notch 856, preventing the plunger 716a from advancing within the reservoir barrel 710a. Such a plunger lock is most useful during priming of the system and when deflating the balloon.

The syringe assembly 800 is preferably operated in conjunction with an inflation adapter 54 and balloon catheter 70 in a manner similar to the syringe assembly 650 discussed above. Once the balloon is inflated, the adapter is preferably actuated to close the catheter valve 66, thus maintaining balloon inflation. To deflate the balloon, the knob 760a is preferably rotated back to the "0" position, retracting the plunger 716a within the inflation barrel 682a, prior to opening the catheter valve 66. Once the catheter valve 66 is open, the reservoir plunger 716a is retracted to deflate the balloon. When fully retracted, the reservoir plunger 716a is rotated a quarter turn to engage the plunger distal notch 850 and housing lock notch 856 in order to lock the reservoir plunger 716a into place and correspondingly ensure the balloon and catheter remain deflated

V. Alternative Uses for the Dual Syringe System

In addition to providing a highly responsive inflation system for an occlusion balloon, the dual syringe system also has a variety of other uses. For instance, the system could be used to deliver precise amounts of therapeutic drugs or medicine to the patient. The system may also be used for irrigation or aspiration. Additionally, the system can be used to infuse whole blood as is described below.

Typically, whole blood is infused into patients with roller type pumps. One problem associated with this type of pump is that roller mechanisms apply a shear stress that often damages the blood cells with the crushing force of the rollers. The dual syringe system could overcome the problem of damaging the blood by providing a hydrostatic pressure that would provide pressure for the transfusion without causing the damaging forces on the cells. The blood cells, because of their circular shape, can withstand great hydrostatic pressure and therefore would not be damaged. Preferably, the large volume syringe will be used to infuse blood.

A low volume syringe or syringe assembly having features in accordance with the present invention is not limited to use only with the inflation adapter as presented herein.

Other arrangements or assemblies may include syringe embodiments of the present invention. Similarly, the method of the present invention may omit the use of an inflation adapter without loss of benefit from the present invention.

VI. Method for Prevention of Distal Embolization

Described below is an improved method for preventing distal embolization during removal of plaque, thrombi or other occlusions from a blood vessel. A preferred embodiment of the present invention is adapted for use in the treatment of a stenosis or an occlusion in a blood vessel in which the stenosis or occlusion has a length and a width or thickness which at least partially occludes the vessel's lumen. Thus, the method is effective in treating both partial and complete occlusions of the blood vessels. It is to be understood that "occlusion" as used herein includes both complete and partial occlusions, stenoses, emboli, thrombi, plaque and any other substance which at least partially occludes the lumen of the blood vessel.

In a preferred embodiment of the invention, aspiration is performed while advancing a guidewire across the site of the occlusion in a proximal to distal direction to prevent distal embolization. An aspiration catheter is delivered over the guidewire to a site just proximal to the site of the occlusion, and, while aspirating, the occlusion in the vessel is crossed with both the guidewire and the catheter in a proximal to distal direction. In a preferred embodiment, the distal tip of the aspiration catheter is no more than 2 cm, more preferably no more than 0.5-1 cm, behind or proximal to the distal tip of the guidewire during crossing. The distal end of the aspiration catheter is then moved in a distal to proximal direction across the occlusion, while continuously aspirating. This process ensures the removal of any particles which may be created during the delivery of the guidewire to a position distal to at least a portion of the occlusion. Aspiration from proximal to distal, and distal to proximal, can be repeated as many times as necessary to completely aspirate all particles. These steps are all performed prior to occlusion of the vessel at a site distal to the occlusion and treatment of the occlusion. It should be noted that, as used herein, "proximal" refers to the portion of the apparatus closest to the end which remains outside the patient's body, and "distal" refers to the portion closest to the end inserted into the patient's body.

The aspiration method disclosed herein can be used in any vessel of the body where the pressure is at least 0.2 psi at any time during the diastolic/systolic cycle of the heart, and, preferably, is about 1.2 psi, and is capable of providing a flow rate of at least 5 cc/minute when not occluded. Thus, although the pressure within any vessel may fall below 0.2 psi during relaxation between heartbeats, so long as the pressure created by the heartbeat rises to at least 0.2 psi, the pressure within the vessel will be sufficient.

The present method is particularly suited for use in removal of occlusions from saphenous vein grafts, coronary and carotid arteries, and vessels having similar pressures and flow.

In a preferred embodiment of the method of the present invention, a guide catheter is first introduced into the patient's vasculature through an incision made in the femoral artery in the groin and is used to guide the insertion of other catheters and devices to the desired site, as described above. A guidewire is then advanced until its distal end reaches a site proximal to the occlusion. Fluoroscopy is typically used to guide the guidewire and other devices to the desired location within the patient. The devices are frequently marked with radiopaque markings to facilitate visualization of the insertion and positioning of the devices within the patient's vasculature. It should be noted that at this point, blood is flowing through the vessel in a proximal to distal direction.

In contrast to previous methods, in one embodiment the guidewire does not cross the occlusion prior to aspiration with an aspiration catheter or other suitable catheter which can provide aspiration pressure. Instead, an aspiration catheter is inserted over the guidewire and the two are simultaneously or concomitantly moved past the occlusion, proximal to distal, while aspirating, to prevent material which dislodges or breaks off the occlusion from entering the vasculature and producing distal emboli. The method is illustrated in **FIGURES 52 and 53** and described in detail below. After crossing of the occlusion by the aspiration catheter and guidewire while aspirating, the aspiration catheter is moved in a distal to proximal direction, also while aspirating. The aspiration catheter is then removed, and therapy performed on the occlusion.

A guidewire having an occlusive device on its distal end is preferably used in the present method. The method can be effectively carried out, however, using a number of guidewires or catheters that perform the function of occluding the vessel and allowing for

the slidable insertion of various other catheters and devices. For example, a guidewire having an expandable device such as an inflatable balloon, filter, expandable braid or other mechanical occlusive device attached at its distal end can be used. The expandable occlusive device should be capable of preventing the migration of particles and debris from the working area, either through total or partial occlusion of the vessel. The occlusion of the vessel need not be complete. Substantial occlusion of the vessel can be sufficient for purposes of the present method.

As the guidewire and aspiration catheter cross the occlusion, blood enters the vessel and keeps any particles dislodged during the procedure from flowing in a distal to proximal direction. In addition, the blood pressure and flow provides the irrigation necessary for aspiration. As noted above, the blood pressure in the vessel is preferably at least about 0.2 psi, and the vessel is capable of providing a flow rate of at least about 5 cc per minute when not occluded.

After the distal end of the guidewire having an occlusive device is delivered past the site of the occlusion and aspiration is complete, the occlusive device is activated, occluding the vessel at a site distal to the site of the occlusion. Once the blood vessel is occluded, therapy can be performed to remove or reduce the occlusion. A therapy catheter can be used if desired. The therapy catheter can be any of a number of devices, including a balloon catheter used to perform angioplasty, a catheter which delivers a stent, a catheter for delivering enzymes, chemicals, or drugs to dissolve and treat the occlusion, an atherectomy device, or a laser or ultrasound device used to ablate the occlusion. Alternatively, the therapy catheter can be eliminated and use of the guide catheter or the aspiration catheter alone can be used to aspirate the occlusion. This method is especially useful to remove emboli from the coronary arteries following acute myocardial infarction, because the aspiration catheter can be made small enough to enter the coronary arteries.

Once the desired therapy is performed, the therapy catheter is withdrawn from the patient's body and the aspiration catheter can once again be delivered over the guidewire. The aspiration catheter can ride over the guidewire with the guidewire inserted through the aspiration lumen of the catheter. Alternatively, a single operator type aspiration catheter can be used, in which only a portion of the aspiration catheter rides over the guidewire, which is inserted into a separate guidewire lumen.

The method of the invention shown in **FIGURE 52** can be used especially following myocardial infarction, for totally occluded vessels and partially occluded vessels defined by TIMI 0-1 flow, and having no major side branch. However, the method of **FIGURE 52** is not intended to be limited only to such applications, and may also be used for vessels having blood flow through side branches. TIMI stands for "thrombolysis in myocardial infarction." This value is measured angiographically by injecting a dye and noting the time it takes to clear through the blood vessel. A TIMI of 3 means that the vessel is open. A TIMI of 0 means that the vessel is totally occluded. In a totally occluded vessel, one cannot visualize past the site of the occlusion because the dye will not flow past the occlusion. Because the site cannot be visualized, a distal occlusive device generally cannot be used.

Referring to **FIGURES 52A-H**, a guidewire 900 is inserted into the blood vessel 902 until the distal tip is just proximal to occlusion 904 (**FIGURE 52A**). An aspiration catheter 906 is delivered over the guidewire 900 so that the distal end of the guidewire 900 and the distal end of the aspiration catheter 906 are just proximal to the occlusion 904 (**FIGURE 52B**). Aspiration is performed while crossing or advancing past the occlusion 904 with the distal end of the guidewire 900, in a proximal to distal direction (**FIGURE 52C**). In other words, both the aspiration catheter 906 and the guidewire 900 are moved in a proximal to distal direction across the occlusion 904 while aspirating through the distal end of the aspiration catheter. Aspirating while crossing in this manner thus removes any particles that may be broken off due to crossing of the occlusion. The distal end of the aspiration catheter 906 is then moved back in a distal to proximal direction while aspirating (**FIGURE 52D**) to further remove particles. Blood flow into the aspiration catheter 906 is indicated by the arrows. The proximal to distal, then distal to proximal, aspiration may be repeated one or more times if desired to ensure removal of emboli or particles formed during movement of the devices across the occlusion 904. After aspiration, TIMI flow may be determined.

The aspiration catheter 906 is then removed and the guidewire 900 is then exchanged for a guidewire 907 having an occlusive device on its distal end 908 (e.g., GUARDWIRE, PercuSurge, Sunnyvale, CA) (**FIGURE 52E**). Further details of an exchange catheter are described in assignee's copending application entitled EXCHANGE

CATHETER AND METHOD OF USE, Application Serial No. 09/026,464, filed February 19, 1998, the entirety of which is hereby incorporated by reference. Alternatively, the aspiration catheter may remain in place for delivery of guidewire 907 to aspirate any additional particles that may break free of occlusion 904 while the guidewire 907 crosses the occlusion, such as described with respect to **FIGURE 53** below. In this embodiment, the aspiration catheter itself may be used as an exchange catheter. The occlusive device 908, such as a balloon, at the end of the guidewire 907 is advanced to a site just distal the site of the occlusion 904, and the occlusive device 908 is activated to prevent downstream migration of particles and debris (**FIGURE 52F**). Therapy can then be performed on the occlusion 904, if desired. For example, an angioplasty catheter 910 can be delivered to the occlusion 904 and the balloon inflated to open the vessel (**FIGURE 52G**). Stenting therapy may also be used. After therapy, the aspiration catheter 906 can be reintroduced to the site to perform further aspiration of particles and debris created during therapy (**FIGURE 52H**). This aspiration may occur in a similar manner as described above, with the distal end of the aspiration catheter moving in a proximal to distal direction across the occlusion 904 while aspirating, and then in a distal to proximal direction across the occlusion 904. After aspiration, the occlusive device is deactivated. If desired, TIMI flow is again determined after therapy and aspiration.

Referring now to **FIGURES 53A-G**, the second preferred method of the invention is used especially for partially occluded vessels, defined by TIMI flow of 1-2, having no major side branch. However, as above, the method of **FIGURES 53A-G** is not intended to be limited only to such applications. A guidewire 907 with an occlusive device such as a balloon at its distal end 908 is inserted into the vessel 902 to a location just proximal to the occlusion 904 (**FIGURE 53A**). An aspiration catheter 906 is delivered over the guidewire 908 so that the distal ends of the guidewire 908 and aspiration catheter 906 are both just proximal to the occlusion 904 (**FIGURE 53B**). Aspiration is performed while crossing or advancing past the occlusion 904 with the distal ends of the guidewire 908 and aspiration catheter 906, in a proximal to distal direction (**FIGURE 53C**). Then the distal end of the aspiration catheter 906 is moved back in a distal to proximal direction while aspirating (**FIGURE 53D**). Blood flow into the aspiration catheter 906 is indicated by the

arrows. The proximal to distal, then distal to proximal aspiration may be repeated one or more times if desired. After aspiration, TIMI flow may be determined.

The occlusive device on the guidewire 908 is then activated to prevent downstream migration of particles and debris (**FIGURE 53E**). The aspiration catheter is preferably removed prior to activation of the occlusive device. Therapy can now be safely performed on the occlusion 904, if desired. For example, an angioplasty catheter 910 can be delivered to the occlusion 904 over the guidewire and the balloon inflated to open the vessel (**FIGURES 53F-G**). Stenting therapy may also be used. The aspiration catheter 906 is then reintroduced to the site to perform further aspiration of particles and debris created during therapy (**FIGURE 53G**). Aspiration preferably occurs with the distal end of the aspiration catheter moving in a proximal to distal direction across the occlusion 904 while aspirating, and then in a distal to proximal direction across the occlusion 904. After aspiration, the occlusive device is deactivated. If desired, TIMI flow after aspiration may be determined.

FIGURES 54A-F illustrate another embodiment in which a guidewire 907 with an occlusive device 908 is delivered to a location distal to an occlusion 904. As shown in **FIGURE 54A**, the occlusion 904 is first crossed with the occlusive device 908, which is preferably a balloon, such that the occlusive device 908 is distal to the occlusion 904. An aspiration catheter 906 is preferably delivered over the guidewire 907 until the distal end of the aspiration catheter is proximal to the occlusion 904 (**FIGURE 54B**). As shown in **FIGURE 54C**, the balloon 908 is then inflated, and aspiration begins through the distal end of the aspiration catheter. Aspiration continues while the distal end of the aspiration catheter moves in a proximal to distal direction across the occlusion 904 (**FIGURE 54D**). The distal end of the aspiration catheter 906 is then moved back in a distal to proximal direction while aspirating (**FIGURE 54E**) to further remove particles. Blood flow into the aspiration catheter 906 is indicated by the arrows. The proximal to distal, then distal to proximal, aspiration may be repeated one or more times if desired to ensure removal of emboli or particles formed during movement of the devices across the occlusion 904.

The balloon 908 is then preferably deflated (**FIGURE 54F**), and TIMI flow may be determined. Alternatively, the balloon 908 may remain inflated throughout the procedure. The aspiration catheter is preferably removed from the guidewire 907, and

therapy is performed, such as with a therapy catheter 906 described with respect to **FIGURES 53E-G** above.

Further details regarding aspiration and other methods and apparatus for treating occluded vessels are disclosed in U.S. Patent No. 5,833,650, and assignee's copending application entitled ASPIRATION METHOD, Application Serial No. 09/049,857, filed March 27, 1998, the entirety of both of which are hereby incorporated by reference.

The embodiments of the apparatus and method as described above are provided merely to illustrate the present invention. Changes and modifications may be made from the embodiments presented herein by those skilled in the art without departure from the spirit and scope of the invention, as defined by the appended claims.